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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,699	04/21/2004	Karen M. Cheves	1001.1705101	5388
28075	7590	11/01/2006	EXAMINER	
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			GILBERT, ANDREW M	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/828,699	CHEVES ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Acknowledgements***

1. This office action is in response to the reply filed 9/11/2006.
2. In the reply, the Applicant amended claims 1, 9, 12, 20, 23, and 24. Thus, claims 1-24 are pending.
3. Additionally, the Applicant filed a terminal disclaimer to applications 10/828572 and 10/987001. Thus, the obvious double patenting rejection to the applications has been withdrawn. Furthermore, the Applicant persuasively argued the obvious double patenting rejection to applications 10/614955 and 10/828699 (erroneously added as this is the current application) thus the rejections have been withdrawn. Finally, the Applicant's arguments against the obvious double patenting rejection to 10/447766 are not persuasive and the rejection is maintained (see discussion below).

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 5, 12-14, 16, 23 and 24 rejected under 35 U.S.C. 102(b) as being anticipated by Lary (6306151). In reference to independent claims 1, 12, 23, and 24, Lary discloses a medical device, comprising: an elongate shaft (10) having a proximal end, a distal end, a first lumen (Fig 7) extending therethrough, and a second lumen (Fig 7) extending therethrough; a balloon (13) coupled to the shaft, the balloon having a first

inflated configuration and a second non-inflated configuration, wherein the balloon has a plurality of wings formed therein when in the second configuration (Fig 6); and one or more cutting members (Fig 4, 9) coupled to the balloon, wherein the one or more cutting members each include a traction region (Fig 4, 9) that is configured to improve traction between the balloon and a target site, act as a means for cutting and means for gripping thereon, and has an uneven traction surface (Fig 4, 9). Webster's defines "traction" as "the adhesive friction of a body on a surface on which it moves." Thus, it is the Examiner's interpretation that any region of the cutting member that contacts and engages in frictional movement with the lesion is a traction region.

5. The Applicant's asserts that the Applicant's specification (pg 3, Ins 21-23) statements that the "traction region" of the balloon improves the traction between the cutting members and the target site thus indicates that traction, as recited in the claims, means that the traction created by the traction region of the cutting member and that this traction is something more or different from the traction caused by other "cutting members" lacking a traction region. Consequently, the Examiner's assertion and definition of traction and the traction region is not consistent with the specification (Remarks, pg 9, paragraph 1). The Examiner respectfully disagrees. Page 3, Ins 21-23 reads:

6. "In at least some embodiments, cutting members 20 include a traction member or traction region 23 that may be, for example, adapted and configured to increase traction between catheter 10 (i.e., cutting members 20) and lesion 14."

7. MPEP 2111.01 states that words of a claim must be given their plain meaning unless the applicant has provided a clear definition in the specification. The Examiner notes that not section of the specification provides a clear definition or special definition of "traction" or "traction region". Thus, the Examiner has given the terms the broadest reasonable interpretation, namely that which follows from the Webster's dictionary definition that any region of the cutting member that contacts and engages in frictional movement with the lesion is a traction region. Furthermore, the Examiner notes that the Applicant's specification additionally reads that the "traction region may vary in its form or structural configuration" (pg 4, ln 1) and goes on to cite several examples including saw-tooth projections (pg 4, ln 2). The Examiner notes that Lary clearly has a traction region, including one having saw-tooth projections (Fig 9).

8. In reference to claims 2-3, 5, 13-14, and 16 (see Fig 9 showing saw-tooth projections having up and down undulations).

9. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Vigil et al (5336234). In reference to independent claims 12, Vigil et al ('624) discloses a medical device, comprising: an elongate shaft (14) having a proximal end, a distal end, a first lumen (14) extending therethrough; a balloon (12) coupled to the shaft, the balloon having a first inflated configuration and a second non-inflated configuration, wherein the balloon has a plurality of wings formed therein when in the second configuration (Fig 2); and one or more cutting members (19) coupled to the balloon, wherein the one or more cutting members each include a traction region (Fig 6, 7) that is configured to improve traction between the balloon and a target site and act as a means for cutting and means

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for gripping thereon. Webster's defines "traction" as "the adhesive friction of a body on a surface on which it moves." Thus, it is the Examiner's interpretation that any region of the cutting member that contacts and engages in frictional movement with the lesion is a traction region. (See above discussion of the Examiner's reasoning with regards to "traction" and "traction region").

10. Claims 1 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Vigil et al (5320634). In reference to independent claims 1 and 24, Vigil et al ('634) discloses a medical device, comprising: an elongate shaft (14) having a proximal end, a distal end, a first lumen (14) extending therethrough, a second lumen (col 4, Ins 63-64); a balloon (12) coupled to the shaft, the balloon having a first inflated configuration and a second non-inflated configuration, wherein the balloon has a plurality of wings formed therein when in the second configuration (Fig 3b); and one or more cutting members (31) coupled to the balloon, wherein the one or more cutting members each include a traction region (Fig 3a, 4a-4b) that is configured to improve traction between the balloon and a target site and act as a means for cutting and means for gripping thereon.

Webster's defines "traction" as "the adhesive friction of a body on a surface on which it moves." Thus, it is the Examiner's interpretation that any region of the cutting member that contacts and engages in frictional movement with the lesion is a traction region. (See above discussion of the Examiner's reasoning with regards to "traction" and "traction region").

11. Claims 20-22 rejected under 35 U.S.C. 102(b) as being anticipated by Barath (5797935). Barath ('935) discloses a medical device, comprising: an elongate shaft (Fig

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3-6) having a proximal end, a distal end, a first lumen extending therethrough; a balloon (34) coupled to the shaft; one or more cutting members (12) coupled to the balloon, wherein the one or more cutting members each include a traction region that is configured to improve traction between the balloon and a target site (12, Figs 2-6) ; see above discussion regarding the Examiner's definition of traction and traction region) and wherein the cutting members each include a proximally extending connector wire and a distally-extending connector wire that are both attached to the shaft (24, Fig 1); wherein the proximally-extending connector wire and the distally-extending connector wire are connected to the shaft at opposing sides of the balloon (Fig 1, 3; col 4, lns 3-54; col 5, lns 16-38); wherein the cutting members are not directly attached to the balloon (Figs 1, 3; col 5, lns 16-20).

12. Claims 9-11, 20-22 rejected under 35 U.S.C. 102(b) as being anticipated by Barath (5616149). Barath ('149) discloses a medical device, comprising: an elongate shaft (Figs 15) having a proximal end, a distal end, a first lumen extending therethrough, and a second lumen (col 4, lns 5-20) extending therethrough; a balloon (2) coupled to the shaft; one or more cutting members (6) coupled to the balloon, wherein the one or more cutting members each include a traction region that is configured to improve traction between the balloon and a target site (Fig 14-16); see above discussion regarding the Examiner's definition of traction and traction region) and wherein the cutting members each include a proximally extending connector wire and a distally-extending connector wire that are both attached to the shaft (Fig 14-16); wherein the proximally-extending connector wire and the distally-extending connector wire are

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connected to the shaft at opposing sides of the balloon (Fig 14-16); wherein the cutting members are not directly attached to the balloon (Fig 14-16).

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 4, 6, 8, 15, 17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lary in view of Grayzel et al (6942680). Lary discloses the invention substantially as claimed except for expressly disclosing wherein the undulations curve from side to side, a plurality of bumps on the cutting members, and a saddle shaped region of the cutting members. Lary does disclose that various cutting member configurations can be used. Grayzel et al teaches that it is known to have the undulations curve from side to side (Fig 3), a plurality of bumps on the cutting members (Figs 1-2, 8a-11), and a saddle shaped region of the cutting members (Figs 6a-b) for the purpose of having projections that can engage a lumen to incise or pierce an occlusion when the chamber is expanded. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cutting members as taught by Lary with the undulations, bumps, and saddle-shaped regions as taught by Grayzel et al for the purpose of having projections that can engage a lumen to incise or pierce an occlusion when the chamber is expanded.



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15. Claims 6-7, 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lary in view of Bradshaw (6450988). Lary discloses the invention substantially as claimed except for expressly disclosing the traction rejection is defined by a plurality of bumps disposed on the cutting members or by a helical region of the cutting members. Lary does disclose that various cutting member configurations can be used. Bradshaw teaches that it is known to have the traction rejection is defined by a plurality of bumps disposed on the cutting members or by a helical region of the cutting members (Fig 1, 2, 4) for the purpose of forming auxiliary perfusion channels. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cutting members as taught by Lary with the helical region and bumps as taught by Bradshaw for the purpose of forming auxiliary perfusion channels.

### ***Double Patenting***

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-8, 12-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/447766. Although the conflicting claims are not identical, they are not patentably distinct from each other. The Examiner notes that the copending application has a inherent traction region on the cutting members. See discussion above in regards to the Examiner's interpretation of traction and the traction region.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Response to Arguments***

18. Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wang et al (2003/0163148); Konstantino et al (2004/0243158).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read 'AG' with a stylized flourish.

Andrew Gilbert

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

A handwritten signature in black ink, appearing to read 'Kevin C. Sirmons'.